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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,303

03/09/2004

Gary Weller

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7590

10/12/2010

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

10/12/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/797,303	<b>Applicant(s)</b> WELLER ET AL.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2/10; 9/7/10</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This action is in response to applicant's amendment received on 08/03/2010.

#### *Information Disclosure Statement*

1. The information disclosure statements (IDS) submitted on 09/02/2010 and 09/07/2010 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Pub. No. **2003/0132267**).

Adams et al. disclose a cartridge assembly having a longitudinal axis (see embodiment of Figures 22-25), the cartridge assembly having a first tissue acquisition member ("stapler member") **17** pivotable about the longitudinal axis or a longitudinal hinge **60** in relation to a second tissue acquisition member ("anvil member") **10** between open and closed configurations; each tissue acquisition member including a tissue receiving cavity (between the hinge and **17d** and between the hinge and **10d**, wherein

Art Unit: 3734

acquisition is met by holding tissue) sized to receive a fold of stomach tissue, the tissue receiving cavity being coupled to a vacuum port; and a stapler **17d** disposed on the first tissue acquisition member and the second tissue acquisition member for stapling the fold of stomach tissue (paragraph 112).

Adams et al. teach utilizing suction in another embodiment (paragraph 100), but does not expressly disclose each tissue receiving cavity being coupled to a vacuum port. However, it would have been obvious to one of ordinary skill in the art to provide a vacuum port that is coupled to each receiving cavity in the embodiment of Figures 22-25 in order further “draw a tissue section into the gap between the anvil member 10 and the proximal housing 12” and to prevent debris from accumulating between the two acquisition members with the help of a shield 31 (paragraph 100) and since there are many other variations of the embodiments within the teaching of the present invention that those skilled in the art will understand (paragraph 135).

4. Claims 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Pub. No. **2003/0132267**) in view of **Deem et al.** (U.S. Patent No. **6,558,400**).

Adams et al. disclose the claimed device except for a bioabsorbable septum removably positioned between the first tissue acquisition member and the second acquisition member which projects radially outward from the longitudinal hinge, or an expandable element

Deem et al. teach a removable septum **196** projecting radially outward from between two first and second members (Figure 10, col. 11, line 57 to col. 12, line 3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a septum, as taught by Deem et al., to the device of Adams et al. in order to damage contacting tissue to speed healing time (col. 11, lines 41-46).

Deem et al. also teach an expandable member or balloon **52** (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an expandable member, as taught by Deem et al., to the device of Adams in order to stabilize the device during a procedure (col. 8, lines 26-27).

Although neither Adams et al. nor Deem et al. teach a septum that is made of bioabsorbable material selected from the group consisting of polylactic acid (PLA), poly(lactic-co-glycolic acid) (PLGA), and polyglycolic acid (PGA), it would have been obvious to one of ordinary skill in the art at the time of invention to provide a bioabsorbable material since it is a biocompatible material and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

### ***Response to Arguments***

5. Applicant's arguments filed 08/03/2010 have been fully considered but they are not persuasive.

6. Applicant argues that Adams does not teach a first tissue acquisition member ("stapler") 17 and a second tissue acquisition member ("anvil") 10 because the

Art Unit: 3734

combination of the staple and anvil do not acquire tissue but rather tissue must be brought to the staple/anvil combination and that the combination can be deemed as a single tissue acquisition member, not first and second tissue acquisition members. The examiner disagrees. The term "acquisition" in tissue acquisition member broadly defines gaining or attaining or coming into possession of the tissue, and does not structurally describe how tissue is gained, or in this case is held into contact with the staple 17 and anvil 10 combination, and therefore Adams reads on this limitation. A combination of parts such as staple 17 and anvil 10 may both separately be described as tissue acquisition members even though they work together to acquire tissue.

7. Applicant also argues that adding another vacuum port would not prevent debris from accumulating between the two acquisition members, but rather the suction of the vacuum port brings in debris into the device. The examiner clarifies, as maintained above, that it would have been obvious to one of ordinary skill in the art to provide a vacuum port that is coupled to each receiving cavity in the embodiment of Figures 22-25 in order further "draw a tissue section into the gap between the anvil member 10 and the proximal housing 12" and to prevent debris from accumulating between the two acquisition members with the help of a shield 31 (paragraph 100) and since there are many other variations of the embodiments within the teaching of the present invention that those skilled in the art will understand (paragraph 135).

8. Also, the applicant argues that incorporating vacuum ports into the tissue acquisition members themselves would require a complete overhaul of Adam's device. However, it is not recited that the vacuum ports be incorporated within the tissue

Art Unit: 3734

acquisition cavities themselves, but rather that they each be "coupled to a vacuum port" or be connected to the vacuum port within the same device, and therefore utilizing suction through the endoscope of the device reads on this limitation.

9. Applicant argues that Adams does not necessarily teach that two folds of stomach tissue may be accommodated in the stapler/anvil combination. However, in paragraph 67 Adams acknowledges that those skilled in the art may vary the sizing of the device depending on the amount of tissue to be acquired, and therefore reads on this limitation.

10. Next, applicant argues that Adams does not teach a stapler on a first tissue acquisition member because the first tissue acquisition member is cited as the stapler 17. As clarified above, a tissue acquisition member 17 has a stapler 17d and a tissue receiving cavity (between the hinge and 17d), and therefore reads on the limitation.

11. Applicant also argues that there would be no motivation to damage the tissue by a septum in Adams since there is no need to induce damage to the tissue that is excised or resected, wherein Deem teaches abrading the septum against healthy tissue to promote adhesion. However, before approximating the surrounding tissue created by the excision, it may be desirable to further incorporate other treatments applied by the septum including heating, freezing, or chemical damage (paragraph 105) that is known in the art to encourage a "more vigorous healing response" than would be created by just an incision.

12. Lastly, applicant argues that Deem has an expandable element or balloon that stabilizes the bougie, and not the stapler, therefore it would not be obvious to modify the

Art Unit: 3734

device of Adams with the balloon of Deem. However, the teaching of an expandable element still would be appreciated by one of ordinary skill in the art as a stabilizing element to facilitate stapling of tissue, and therefore would have been an obvious modification.

### ***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/TODD E. MANAHAN/  
Supervisory Patent Examiner, Art Unit 3734